REMARKS

On page 2 of the Office Action the Examiner objected to the informalities of the specification because the section headings are underlined and boldface throughout the disclosed specification. Applicant requests reconsideration in view of this amendment.

The specification has been amended to substitute appropriate section headings that are not underlined or in boldface. These section headings have been selected from the guidelines set forth in 37 C.F.R. § 1.77(b). For these reasons, it is requested that the objection to the specification as being informal be withdrawn.

On page 3, item 4 of the Office Action, the Examiner rejected Claims 1, 3-5, 7-11 and 14-18 under the provision of 35 U.S.C. 102(b) as being anticipated by United States Patent No. 5,845,255 to Mayaud (hereinafter the `255 Patent or "Mayaud").

Reconsideration is respectfully requested.

A prima facie case of anticipation, according to the Federal Circuit, "requires the presence in a single prior art disclosure of each and every element of the claimed invention." *Lewmar Marine v. Barient, Inc.*, 3 U.S.P.Q.2d 1766, 1767 (Fed. Cir. 1987). Mayaud does not meet that standard.

The claims, as presently amended, are directed to an internet-based universally compiled data repository system with access to a locally compiled database for medical product information. The system provides for the novel access and dissemination of product information for the safe and rational use of medications by a user at the actual point of administration of medication to hospital based patients. As such, the system of the present invention provides a final safety check before a medication is received by a patient.

Additionally, the system provides product information for any type of patient administered medication, for example, specially prepared intravenous solutions or combinations of oral medications. Upon scanning a coded medication, the product information provided includes specially defined and formatted product descriptions, including NDC numbers, safety codes, product scan codes, product recall information, product equivalency information, and company specific product information for specific technology products. The system provides a user access data auditor which provides a

user data access audit trail, a programmed system computer for processing and storing medical product information, and an input and output device operatively interconnected to the programmed system computer means.

Applicant acknowledges that Mayaud describes a "computer-implemented prescription creation system" the system being for use by "a prescriber to create an electronic prescription prescribing a drug to treat a condition... at a point-of-care ... and being useable by a pharmacist to dispense the prescribed drug" See Claim 1 of the `255 patent.

The Examiners pointed out Mayaud teaches a "[D]ata warehouse," and "a database containing medical product information comprising one or more of the following fields..." and that, the fields contain information such as NDCs, safety codes, product scan codes, recall information and the like. However, a fair reading of Mayaud reveals a database system that is restricted by "**prescriber**" needs and **third party information**. As such, Mayaud is not a true "universal" database.

The instant application discloses an independent UMSCDR system having two design methods for data: direct read and/or connection via the Internet to the **FDA National Drug Code (NDC) Directory or manual update by clinically trained personnel**. Further, the system administrator may grant access, such as to designated members of the FDA for dissemination of recall information and to clinical support personnel employed by a service provider such as IdentityHealth Technologies® for product description maintenance. See Specification at page 11.

In contrast, Mayaud is replete with examples whereby the database is comprised of multiple third party information which is limited to "approved drugs classified by conditions," "selective listing of drug by conditions" (see Mayaud at Col 5, lines 44-50), "formularies" (see Col. 8, line 27), "[P]harmaceutical and managed care companies can gain marketing benefits" (see Col. 23, lines 47-50), "formulary changes" (Col. 33, line 32), and aggregation of data "for market research purposes" (see Col. 13, lines 49-51).

Specifically, Mayaud discloses "[I]n other words, an aim of the invention is to provide an intelligent, knowledgeable computerized prescription pad," (see `255 patent at

Col. 9, lines 65-67), for use by an authorized prescriber to help him/her navigate the plethora of third party formularies.

In sharp contrast, the presently claimed data repository system for medical product information inventively provides immediate dissemination of medical product information, to a nurse, physician's assistant, pharmacist or any other authorized person administering medication to a hospital based patient. Final verification is made by "scanning" the medication into the system prior to administration. In essence, a final safety evaluation of the medication being administered to the patient is performed using the claimed system.

Mayaud neither teaches nor suggests the use of the data system for a "final verification." Specifically, Mayaud's system is used to "assist" the "average prescribing physician" at a point of patient care, so that the prescription is usable by a pharmacist to dispense drugs (see Mayaud at Col. 4, lines 30-35).

The Examiner further noted that Mayaud teaches methods for creating and using drug recall information. In this regard, it must be noted that Mayaud neither teaches nor suggests the use of this information immediately prior to the administration of medication to inpatients, as presently claimed. More specifically, **Mayaud teaches a prescription management system for use with a portable personal computer to assist the prescribing physician with formularies, dosages, interactions and related information to patients in a non-institutional setting, and not as a supporting medication safety program at healthcare institutions.**

The presently claimed invention provides a data repository system for the safe and rational use of medications at the time of their administration to an institution based patient, which is not taught nor suggested in the cited prior art. For these reasons the §102(b) rejection over Mayaud is not proper. Withdrawal of the rejection is therefore respectfully requested.

On page 8 of the Office Action the Examiner rejected Claims 2, 6 and 12-13 under 35 U.S.C. § 103(a) as being unpatentable over Mayaud in view of Portwood et al., United States Patent No. 6,305,377 (hereinafter "Portwood").

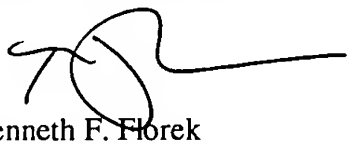
Reconsideration is respectfully requested.

Applicant acknowledges that Portwood describes a medication "compliance system" wherein GPI and NDC identification codes may be used; however, the combination of Portwood's medication identifiers and Mayaud's assisted prescribing system would not solve the problem of supporting a medication safety program for institution based patients at the time of administration of a medication.

Further, it is impermissible to use the presently claimed invention as an instruction manual or template to piece together the teachings of the cited prior art so that the claimed invention is rendered obvious. *In re Gorman*, 933 F. 2d 982, 987, 18 USPQ2d, 1885, 1888 (Fed. Cir. 1991). See also, *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985). Further, the courts have stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d at 1600 (Fed. Cir. 1988). As such, removal of the rejection under 35 U.S.C. §103(a) is therefore respectfully requested.

In light of the foregoing, favorable consideration is respectfully requested and earnestly solicited at this time.

Respectfully submitted,



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